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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,309	07/20/2006	Walid Ali	US040114	9203

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EXAMINER
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BIEGEL, RONALD L

ART UNIT	PAPER NUMBER
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2857

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/597,309	<b>Applicant(s)</b> ALI, WALID	
	<b>Examiner</b> RONALD L. BIEGEL	<b>Art Unit</b> 2857	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 June 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>20 Jul 2006</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Specification*

The disclosure is objected to because of the following informalities:

**A.** Algebraic notation for *signals* and *samples* is confusing. Applicant denotes *samples* with small letters ( $s_1...s_n$ ) and *signals* with capital letters ( $S_1...S_n$ ) in the claims and page 1 of the Spec. In contrast, from page 5 to the end of the specification, Applicant refers to *signals* with small letters.

**B.** Equations 2 and 3 appear to have typos. Eq. 2 has the numerator raised to the power  $"/2$  which is probably intended to be  $"1/2$ " or  $"3/2$ ". Eq. 3 is missing an upper index that was probably intended to be "I".

Appropriate correction is kindly requested.

### ***Claim Rejections - 35 USC § 101***

Claims **1-12** are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The test for a method claim is whether the claimed method is (1) tied to a particular machine or apparatus, or (2) transforms a particular *article* to a different state or thing. Claims **1**, **6**, and **11** recite method claims that do not bring about a transformation in nature nor is the claimed process tied to an article of manufacture or apparatus. For that reason they are rejected under 35 USC 101 as non-statutory.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims **1**, **6**, **11**, **13**, **16**, and **20** are rejected under 35 U.S.C. 112, second

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paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention.

The limitation "*highly*" before the word "correlated" is indefinite. "Correlated" is a term that broadly defines a relationship between two objects and the word "*highly*" is indefinite. Thus, the combination "highly correlated" lacks the sufficient limitation to be considered definite. Amendment is requested. If Applicant intended "correlate" to refer to the mathematical functions "cross-correlate" or "auto-correlate" then Applicant is kindly asked to amend the claim language appropriately.

Dependent claims **2-5, 7-10, 12, 14, 15, and 17-19** contain the language of the independent claims they depend from and stand rejected for the same reasons.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**I.** Claims **1, 2, 4-6, 13-15, and 20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Snyder et al., US Patent No: 6,287,328 B1 (hereinafter Snyder).

Regarding Claim **1**, Snyder teaches a method for monitoring a patient by testing a plurality of monitored signals (Snyder, col. 4, Ins. 10-15) to determine whether an artifact is present in the monitored signals. Snyder teaches these are called "artifact signals". Snyder does not teach that a null hypothesis test is applied against "pairs of

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samples of highly correlated monitored signals *of the plurality of monitored signals*" nor does Snyder teach a step of "determining an artifact may exist in one of the plurality of monitored signals when a likelihood that the null hypothesis is true falls below a predetermined confidence level." See Snyder Claim 1, Ins. 3-5. But, Snyder teaches that his inference processor analyzes "correlation signals to determine a *degree* of corruption of the event signal..." and that "...inference processors are typically selected from the group consisting of ...probability estimators and statistical classifiers". See Snyder, col. 4, Ins. 55-60 and col. 7, Ins. 55-63). The examiner notes that Applicant's invention in the field of medical diagnostics is drawn to a method and apparatus for discriminating between a common mode signal and an artifact or corrupted event signal. Snyder teaches that in the area of medical diagnostics and instrumentation artifact signals are dangerous since their appearance in a patient monitoring device could inadvertently cause a clinician to make an incorrect diagnosis of a patient's heart condition resulting in a dangerous and potentially fatal course of action by the medical staff (Snyder, col. 1, Ins. 23-33). In view of this teaching by Snyder, it would have been obvious to one of ordinary skill in the art at the time the invention was made to implement the disclosed inference processor of Snyder using the hypothesis testing procedure claimed by the Applicant for the desired advantage of preventing injury or death to a patient by mistakenly administering a shock to patient's heart.

Turning to Claims **2** and **14**, Snyder teaches receiving a plurality of monitored signals from the patient, each of which provide information as to the health of the patient (Snyder, col. 4, 1 Ins. 42-51).

As to Claims **4** and **15**, Snyder teaches the hypothesis testing includes generating a probability that each of the monitored signals includes an artifact (Snyder, col. 6, Ins. 6-10).

As to Claim **5**, Snyder teaches an output signal to alert an operator that at least one of the monitored signals includes an artifact when the generated probability exceeds a predetermined threshold (Snyder, col. 9, Ins. 57-61).

Regarding Claim **6**, Snyder teaches detecting an artifact in one or more samples of a plurality of monitored signals comprising: calculating, for each of the one or more samples of the plurality of monitored signals (Snyder, col. 4, Ins. 10-15), a cross probability of observing the sample and another sample assuming a null hypothesis is true (Snyder discloses an inference processor that performs statistical calculations, col. 5, Ins. 36-50, and the cross-probability is a statistical function within the meaning of Snyder.), wherein the null hypothesis is that the sample and the other sample have the same distribution as a stored version of the sample of the plurality of monitored signals (statistical testing is taught by Snyder, col. 5, Ins. 36-50); calculating a confidence level associated with each of the cross probabilities; repeating the calculating steps for all combinations of pairs of highly correlated monitored signals of the plurality of monitored signals; summing, for each sample, all of the cross probabilities associated with a pair of highly correlated signals that includes the sample (statistical testing is taught by Snyder, col. 5, Ins. 36-50); and outputting a result for each sample as a probability of not including an artifact in the sample, wherein one or more of the probabilities of not including an artifact lies below a predetermined threshold indicating to a user that one or

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more samples associated with one or more of the probabilities may include an artifact (statistical testing is taught by Snyder, col. 5, Ins. 36-50).

Turning to Claim **13**, Snyder discloses an apparatus for monitoring a patient comprising: a plurality of leads, each to receive a sample of a monitored signal (col. 8, Ins. 11-24), a memory to store each of the received samples of the monitored signals (Snyder teaches a microprocessor, Fig. 2, no. 10 within the defibrillator, and it would have been obvious to one of ordinary skill in the art that a microprocessor would include memory to store data and the programming needed to process that data in order to make the device more efficient, user-friendly, and versatile); and a processor coupled to the memory, said processor being programmed to: employ hypothesis testing against each of a plurality of monitored signals to determine whether an artifact is present in the plurality of monitored signals, in which a null hypothesis includes an assumption that pairs of samples of highly correlated monitored signals of the plurality of monitored signals have a predetermined distribution; and determine that an artifact may exist in one of the plurality of monitored signals when a likelihood that the null hypothesis is true falls below a predetermined confidence level as it has been explained for Claim 1. (Snyder teaches using statistical and probability testing to decide if a signal is corrupted (an artifact) at col. 5, Ins. 36-50 which meets the limitations of Claim 13).

**II.** Claim **20** is rejected under 35 U.S.C. 103(a) as being unpatentable over Snyder et al. Patent No.: US 6,287,328 (hereinafter Snyder).

Regarding Claim **20**, Snyder teaches the method as explained for Claim 1.

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However, Snyder does not disclose a computer readable media encoded with a plurality of instructions to cause a processor to perform the explained method.

However, computer performance is both fast and accurate; two highly desirable characteristics that are important when medical personnel have to make critical decisions on patients during life-threatening situations. Computers can take large quantities of data about a patient and quickly process it to provide suggested courses of action including administering electrical shocks to a patient as a way to defibrillate a heart during a coronary attack. Also, a computer is less prone to error when making critical decisions and that is a characteristic that is highly desirable if saving lives is a high priority. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to encode the claimed algorithm on a computer readable medium to cause a processor to perform the claimed steps.

Also, hypothesis testing is contained in most statistics handbooks, and is normally part of the training of engineers and scientist. Hence this additional feature does not involve any skill or ability beyond that to be expected of one of ordinary skill in the art. Hence, an obvious expedient.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ronald L. Biegel whose telephone number is (571) 272-2523. The examiner can normally be reached M-F 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eliseo Ramos-Feliciano can be reached on (571) 272-7925. The fax phone



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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. L. B./  
Examiner, Art Unit 2857

/Eliseo Ramos-Feliciano/  
Supervisory Patent Examiner, Art Unit 2857